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Biotechnology

Annual Report

2006

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Report Highlights:

Hungary's biotechnology policy for feed corn production, corn seed production, and soybean product (soybean meal) imports negatively impacts U.S. exports to Hungary. Field corn and seed corn production (about one fifth of the EU's corn crop) is dominated by American varieties. Four biotech varieties passed the evaluation process and are waiting approval, two others are still under field trials. The Government of Hungary (GOH) sent a draft of its coexistence regulation to the European Commission for approval on October 15, 2005. The Commission sent back its detailed opinion on the draft in March 2006. The GOH plans to send its response to the Commission during the summer of 2006, and the revised draft may be presented to the Hungarian Parliament for debate this fall. Legal and technical debates about the coexistence regulation may hamper the commercialization of biotechnology crop varieties in Hungary over the next few years.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
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Executive summary

Hungary's biotechnology policy for feed corn production, corn seed production, and soybean product (soybean meal) imports negatively impacts U.S. exports to Hungary. Field corn and seed corn production (about one fifth of the EU's corn crop) is dominated by American varieties. Four corn varieties passed the evaluation process and are waiting approval, two others are still under field trials. The Government of Hungary (GOH) sent a draft of its coexistence regulation to the European Commission for approval on October 15, 2005. The Commission sent back its detailed opinion on the draft in March 2006. The GOH plans to send its response to the Commission during the summer of 2006, and the revised draft may be presented to the Hungarian Parliament for debate this fall. Legal and technical debates about the coexistence regulation may hamper the commercialization of biotechnology crop varieties in Hungary over the next few years.

Biotechnology Trade and Production--Status of Product Approvals

No biotechnology crop varieties are produced in Hungary. Three varieties have gone through field trials and are waiting registration, including:

Field trials finished in 2003:

MEB 470 BT (DK 440 BTY) MON 810 code number corn borer resistant (MONSANTO)

NX 3035 (Alpha BT) Bt11 code number corn borer resistant (Syngenta)

X 0987ZT MON 810 code number corn borer resistant (Pioneer Hi-Bred Rt.)

The Ministry of Agriculture and Rural Development (MARD) refused to approve the registration of the above varieties because coexistence regulation is not yet in place.

Additional corn varieties subject to field trials include:

MEB 471 RR (DK 440 RR) NK603 code number Roundup Ready tolerant (MONSANTO)

MEB 391 RR (DK 391 RR) NK603 code number Roundup Ready tolerant (MONSANTO)

X1019VT BT code number corn borer resistant (PIONEER Hi-Bred Rt.)

On January 20, 2005, the Government of Hungary (GOH) imposed a moratorium on corn varieties containing the MON 810 event. The moratorium went into effect by a Minister's Decree, and the legal paperwork for the moratorium is now in Brussels for official review. According to MARD sources, the response of the Commission on the ban is expected in the summer of 2006.

The four main reasons for the moratorium were the following:

1). The negative results of an environment effect study. The research carried out in Hungary under the direction of the Plant Protection Institute of the Hungarian Academy of Sciences focused on genetically modified maize DK 440 BTY containing the genetic construction YieldGard™ MON 810. Laboratory and small-scale parcel field experiments showed that the long-term presence of the plant might have adverse effects on the ecosystem. (*Darvas et al. (2003) EFFECT OF POLLEN OF DK-440-BTY (YIELDGARD) BT MAIZE ON THE LARVAE OF INACHIS IO L. (NYMPHALIDAE)* Hungarian Academy of Sciences, Plant Protection Institute, Ecotoxicology Department, Budapest)

2). The need to repeat the late 1990s EU trials using contemporary methodology for this event.

3). The specific ecological conditions of the “Pannonian biogeographic region” (a region containing parts of Hungary, Austria, and Slovenia) questions the validity of risk assessment based on the ecosystems of the older Member States, owing to its different environmental features.

4). Hungary has no coexistence regulation yet.

Hungary is an active participant in the development of biotechnology crops at the basic science level, as well as in the research of the environmental, feeding, etc. effects of these crops in cooperation with other countries.

Hungary does not import biotechnology crops, but imports soybean meal, peanut butter, sauces and other products containing biotech raw materials.

Biotechnology Policy--Regulatory Framework

In the case of green (agricultural) biotechnology, the MARD takes the lead concerning the cultivation, importation, and processing into food/feed. The Hungarian Food Safety Authority (HFSA) under the Ministry of Health (MH) is the top umbrella organization, but most of the administrative responsibilities and the institutional background belong to the MARD. The Ministry of Environment and Water Management (MEW) handles certain biotechnology regulation portfolios and also participates in the work of the Biotechnology Committee (BC). MH is responsible for the red biotechnology (medicinal use), and the Ministry of Economy and Transport (MET) handles foreign trade and strategic investment affairs. Both the MH and the MET are advocates of biotechnology as the key to further economic development but firmly differentiate between red (thought of positively) and green (thought questionably) biotechnology.

The Biotechnology Committee (BC) has a key role in evaluating the applications (new varieties, genes, etc.) although the approval is formally made by the MARD. The Hungarian Academy of Science (MTA) may delegate five members, the relevant Ministries (MARD, MET, MH, MEW) and the Ministry of Education delegate one each, and NGOs may nominate seven delegates (including one by the pro-biotech Zoltan Barabas Biotechnology Association) to the 17 member BC. Civil Servants (government employees) are not members of the BC. Ministries nominate scientists or experts from ‘think tanks’ belonging to their Department. The “independent” BC sets its own rules, supposing that the question is not regulated in the Act No. XXVII. of 1998 On Biotechnology or elsewhere (e.g. 111/2003. (XI.5.) Order of Ministers of MARD, MET, MH, and MEW on Genetic Modification and Like Processes, and their Inspection Authorities).

Administrative and service charges of the Committee and other authorities inspecting biotechnology experiments are set in the 138/2004. (IX.23) Order of the Minister of MARD on the administrative and Service Fees for the Approval of Gene-technology Activities.

Regulatory decisions may be influenced by different political factors, including:

- EU market orientation of Hungary's corn and corn seed production. Traditionally strong cooperation with Austria and Germany, main opponents of GMOs.
- The Hungarian consumer is pragmatic, but domestic and international green organizations are increasingly active in Hungary.

- Politicians, government officers, journalists and sometimes scientists are shy to express their opinions about biotechnology or even participate in topical seminars.

Biotechnology Research

Besides testing biotechnology crop varieties, Hungarian biotechnology laboratories are dealing with the analysis of different GMO materials. Use of these biotechnology materials (for variety field test or any other feeding, environmental effect, etc. trials) must also be approved by the BC. According to a BC decision, stacked events are taken for new events, considering possible cross effects. Lists of biotechnology materials and programs are available at the website of the Godollo Agricultural Biotechnology Center (www.abc.hu) and the website of the EU Commission, Directorate General, Joint Research Centre (<http://biotech.jrc.it>) quoted in ANNEX I.

Researchers of the "Pannonian Region" countries (see page 2, point 3) established the "Pannonian Region Agricultural Biotechnology Association" in June 2006. The partnership of respected scientists and plant breeding and seed business entities from Austria, Czech Republic, Hungary, Slovakia, Slovenia, Romania, Croatia, Bosnia-Herzegovina, Serbia, and Ukraine plan to facilitate regional collaboration, information exchange, and to assist country based biotechnology efforts.

Coexistence Regulation

The MARD finished the drafting and first panel discussions of the Hungarian coexistence regulation in June 2005. The draft was sent for Commission approval on October 15, 2005. The drafting period (first half of 2005) included vivid discussions at different government and NGO forums. Representatives of the biotechnology industry and the Biotechnology Association participated in the work of the Coexistence Working Committee.

The Commission sent back its detailed opinion on the draft to the MARD in March 2006. The Commission's opinion proposed corrections in the draft coexistence regulation.

- In some instances (i.e. the ban of EU listed varieties and the request for further environmental risk assessments) the GOH wants to regulate issues that are harmonized at the EU level.
- In the case of producer liability, the Commission stressed that measures, including liability rules must be proportionate with the objectives and potential risks.

The GOH plans to send back to the Commission its response during the summer of 2006. The revised draft may be presented to the Hungarian Parliament for debate this fall.

The Biotechnology Association, the main lobbying organization of the biotechnology industry, is dissatisfied with the draft. The least acceptable points of the coexistence regulation for the industry are the isolation distances and the required neighbor farmer (landowner) permits. The isolation distance set by the draft for corn is 400 meter, more than double of the distance used in hybrid seed propagation worldwide. Written permit from the neighbor farmer, prior to the application of the GMO variety, is also not necessary in civil liability (as the Commission has indicated). These requirements may "de facto" block the commercialization of biotechnology varieties.

Labeling rules

Act No LXXXII of 2003 on Food (AF) is a general, "umbrella" piece of legislation. The Act does not contain the domestic versions of EU (European Council or Commission) directives,

so it does not need to be revised whenever any EU directive is changed. The domestic directives are contained in the **Hungarian Food Codex (HFC)** or other separate legal rules (such as legislation for Wine, for Mineral Water, and for Meat and Meat Products). General prescriptions of the Act must be applied together with HFC directives and other corresponding regulations.

All kinds of food, including food imported for commercial sale, fall under the ruling of the Act. (Products from other EU member countries are considered as domestic products (§7. (2)) See the AF in English at http://www.fvm.hu/files/elelmiszeripar/elszi_5_en.pdf

Other corresponding regulations include:

19/2004. (Feb 26.) Order of the Min of Agr-Min of Health-Min of Economy On labeling of Foodstuffs

138/2004 (Sep 23.) Order of the Min of Agriculture On the administrative and Service Fees for the Approval of Gene-technology Activities

e.g. -Fees for the approval of commercial sales of GMOs and products thereof

-Fees for the approval of the export-import trade of above products

142/2004. (Sep 30.) Order of Min of Agr-Min of Economy On Some Rules of Gene-technology Activities in Agriculture and Industry

e.g. Labeling of products containing GMOs (above the threshold level).

Hungary is not an importer of biotech products, excluding animal feed. Plant propagation materials (seeds) go through systematic sampling and laboratory analyses. However, for feed and food, where the exporter must declare the quality of the product, only random sampling takes place.

The accredited laboratory for biotechnology testing is the Biomi Kft., a joint venture between the Agricultural Biotechnology Center at Godollo and the Dr. E. Wessling Chemical Laboratory Kft. (www.biomi.hu)

Cartagena Biosafety Framework

Hungary has ratified the Biosafety Protocol. The legislation is the CIX./2004. Act on the Promulgation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The implementation rules of the Act have not yet been prepared.

Capacity Building and Outreach

Post has sponsored government officers, scientists and journalists on agricultural biotechnology programs in the US through the Cochran Fellowship Program over the past few years.

The International Visitor Program of State Department has also been used for sending a Hungarian government official to the United States as part of an outreach activity.

In 2005, the USDA/FAS Biotechnology unit co-sponsored the travel of a Hungarian journalist to participate at the congress of the International Service for the Acquisition of Agri-biotech Applications (ISAAA) in Singapore, March 18-24, 2005. The goal of the Hungarian

participation was to facilitate the establishment of a Hungarian 'node', a national knowledge center, of the ISAAA.

ANNEX

I. Deliberate releases, Plants – Hungary, 2006

TheValue	Notification number	State	Pub. Date	Name of the Institutes or Companies	Project title	Final report
	B/HU/06/02/3	Hungary	21/03/2006	St. Stephen University	Field trials program of maize varieties resistant to certain Coleopteran insects and tolerant to a herbicide (59122 maize)	
	B/HU/06/02/4	Hungary	10/03/2006	St. Stephen University	Field trials program of genetically modified maize resistant to certain Coleopteran insects and tolerant to two herbicides (59122xNK603 maize)	
	B/HU/06/02/5	Hungary	10/03/2006	St. Stephen University	Field trial program of genetically modified maize resistant to certain Lepidopteran and Coleopteran insects and tolerant to two herbicides (59122x1507xNK603 maize)	
	B/HU/06/02/1	Hungary	10/03/2006	St. Stephen University	Field trial program of genetically modified maize varieties resistant to certain Lepidopteran and Coleopteran insects and tolerant to glufosinate-ammonium herbicide (1507x59122 maize)	
	B/HU/06/02/2	Hungary	10/03/2006	St. Stephen University	Field trial program of genetically modified maize varieties resistant to certain Lepidopteran insects and tolerant to two herbicides (1507xNK603 maize)	
	B/HU/05/12/1	Hungary	07/03/2006	Dow AgroSciences Hungary Kft.	Field trial program of genetically modified corn hybrids containing resistance to certain Lepidopteran insects and tolerance to two herbicides.	
	B/HU/05/12/2	Hungary	07/03/2006	Dow AgroSciences Hungary Kft.	Field trial program of genetically modified corn hybrids containing resistance to certain Coleopteran and Lepidopteran insects and tolerance to two herbicides.	